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IMPLEMENTING THE *PEARSON* DECISION

Comments submitted by the Council for Responsible Nutrition at the FDA public meeting, April 4, 2000

RESPONSES TO QUESTIONS POSED BY FDA ABOUT IMPLEMENTION OF THE *PEARSON* DECISION

1. What is the best regulatory approach for protecting and promoting the public health? Specifically, what approach to regulating health claims will: (a) Protect consumers from fraudulent and misleading claims; and (b) provide reliable, understandable information that will allow consumers to evaluate claims intelligently and identify products that will in fact reduce the incidence of diseases? By what criteria should implementation options be judged?

CRN response: CRN believes the public health is protected when consumers have access to meaningful information that is truthful and not misleading, and can use that information to make health choices for themselves and their families. The longstanding requirement of the Food, Drug and Cosmetic Act that all statements made in food labeling should be truthful and not misleading is intended to assure that consumers are protected from fraudulent or misleading claims. In NLEA, Congress attempted to impose a higher burden of proof for health claims. However, the *Pearson* decision clearly indicates that the First Amendment does not permit the agency to prohibit statements that are truthful and not misleading.

The Federal Trade Commission is also charged with preventing claims that are false or misleading, and that agency takes the approach of requiring that health-related claims be substantiated by the quality and quantity of evidence implied by the claim. This results in meaningful discrimination between misleading and truthful claims, as demonstrated by numerous successful enforcement actions.

There may be options, within the basic requirement that all statements be truthful and not misleading, for FDA to provide consumers with more label information about the strength of the evidence for various claims. For example, there was testimony at the hearings of the Commission on Dietary Supplement Labels and there has been talk recently at meetings of various professional associations about the desirability of some kind of rating system which could indicate the strength of the evidence supporting

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statements of nutritional support for dietary supplements. Such a rating system might reasonably be applied to a variety of label claims, possibly including NLEA health claims.

When NLEA in 1990 authorized FDA to permit health claims (specific disease claims) for foods, it also required FDA to determine "based on the totality of publicly available scientific evidence...., that there is significant scientific agreement....that the claim is supported by such evidence." For dietary supplements, NLEA provided that health claims "shall not be subject" to the requirements set forth for conventional foods, but "shall be subject to a procedure and standard, respecting the validity of such claim, established by regulation...." FDA used its discretion to determine by regulation in 1994 that the general requirements for health claims for dietary supplements should be the same as for conventional foods – specifically that all health claims should be based on "significant scientific agreement."

Even if FDA changed its position at this time and established a different standard and procedure for the evaluation of health claims for dietary supplements, the agency would face the same First Amendment issues, unless the standard adopted were the same as the standard set forth in the misbranding provision of the FD&C Act -- namely, that the statement not be false or misleading in any respect.

CRN believes FDA has consistently misinterpreted the "significant scientific agreement" standard to refer to agreement about the strength of the underlying nutrient-disease relationship, rather than to agreement about the truthfulness of the claim, as stated. For example, in the case of omega-3 fatty acids and coronary heart disease, FDA has held that there must be significant scientific agreement about whether omega-3 fatty acids reduce the risk of heart disease. The correct requirement, in CRN's view, would be that there be significant scientific agreement that the statement accurately reflects the state of the evidence. For example, "The weight of the available evidence indicates that diets rich in omega-3 fatty acids may reduce the risk of heart disease, but more research is needed." In other words, there shouldbe symmetry between the claim and the evidence that supports it.

In the *Pearson* decision, the court required that FDA better define "significant scientific agreement" so that petitioners for a health claim could tell whether or not their petition met the requirement. The guidance document made available in December does not really advance this cause. The document is a thorough discussion of the various types of evidence to be taken into account in evaluating any body of scientific data, but provides no insight in determining whether and when "significant scientific agreement" may be said to exist. Thus, CRN believes the agency has not yet fully complied with the court's mandate to more clearly define significant scientific agreement.

The fact remains that, whatever FDA's ultimate definition of significant scientific agreement, and regardless of whether a separate standard is established for evaluating dietary supplement health claims, under *Pearson* it will not be possible to prohibit health claims not meeting the standard. Claims that are truthful and not misleading will have to

be permitted. CRN believes this is in the public interest in that it will both educate consumers about beneficial products and provide an incentive for making more beneficial products available in the marketplace. An FTC report published in 1989, before passage of NLEA but after several years of controversy over health claims being made for fiber and cancer, concluded that the existence of those claims raised consumer awareness about the importance of fiber and also spurred the availability of a wider variety of high-fiber products in the marketplace.

2. Can qualifying language (including disclaimers) be effective in preventing consumers from being misled by health claims based on preliminary or conflicting evidence? How should the agency determine what constitutes an appropriately qualified claim? If the available information is not sufficient to answer these questions, what research needs to be done, and who should be responsible for doing it?

CRN response: The question presumes that FDA will now be required to permit health claims based on preliminary or conflicting evidence. CRN does not believe this is the case. Under the *Pearson* decision, FDA will be required to evaluate whether an unauthorized health claim can qualify as truthful and not misleading with the addition of a qualifier or disclaimer. However, the court specifically indicated that FDA would be free to conclude, in some cases, that the evidence for a claim was so weak that it would be false and misleading regardless of a qualifier or disclaimer. In other words, the court concluded that a disclaimer or qualifier cannot salvage a claim that is fundamentally false or misleading.

The Federal Trade Commission permits the use of qualifying language in advertising claims, and requires that substantiation for a claim be consistent with the level of evidence expressed in the claim. FDA could apply the same reasoning to health claims for foods generally or for dietary supplements specifically. FDA has the capability of conducting consumer research to evaluate consumer understanding of disclaimers, and could also profit from research which has been conducted on this exact point by the Federal Trade Commission.

3. Is there a way to preserve the existing regulatory framework for health claims consistent with the First Amendment?

CRN response: It does not appear possible to preserve the existing regulatory framework for health claims in a manner that is consistent with the First Amendment. It may be possible for FDA to permit a hierarchy of claims, one of which would be an unqualified claim supported by "significant scientific agreement." However, the court clearly indicates that it is not possible to ban statements that fall short of having significant scientific agreement (or of meeting any other specific standard that might be established separately for dietary supplements), if qualifiers or disclaimers can prevent the statements from being false or misleading.

4. If health claims are permitted based on a standard less rigorous than significant scientific agreement, what is the best way to distinguish among claims supported by

different levels of evidence so that consumers are not misled? Does the word "may" in existing health claims accurately communicate the strength of the evidence supporting claims that meet the significant scientific agreement standard, or should other language be used?

CRN response: As indicated above, it may be possible for a hierarchy of claims to be developed, with the level of substantiation indicated by some statement or symbol. CRN believes the word "may" in existing health claims is widely considered to be a hedge or disclaimer. If the question is whether the word "may" helps consumers understand that the current health claims are the strongest statements permitted under FDA's current approach, we believe the answer is no. Some other means of establishing a hierarchy of claims needs to be developed.

5. If health claims are permitted based on a less rigorous standard, what actions can be taken to provide incentives to manufacturers to conduct further research on emerging substance-disease relationships?

CRN response: Creating a hierarchy of claims, with a clear label indication regarding the strength of the evidence for the claim, would provide an incentive for manufacturers to conduct further research to qualify for a higher designation. For example, if claims were rated A, B, and C, a company with a C claim would have incentive to do additional research to qualify for a B claim.

6. The *Pearson* opinion mentions circumstances in which FDA might be justified in banning certain health claims outright (e.g., where the evidence in support of the claim is outweighed by evidence against the claim, or where the evidence supporting it is qualitatively weaker than the evidence against it).

a. How should FDA determine when evidence supporting a health claim is outweighed by evidence against the claim?

CRN response: As CRN understands the spirit of the *Pearson* decision, we would urge FDA not to think in terms of banning claims, but of crafting disclosure requirements that would clearly convey the degree of substantiation for a claim and that would make a weak claim not worth making. For example, if there are 3 studies showing a weak benefit of some substance and 3 studies showing no benefit and 3 studies showing a negative effect, a truthful claim might be, "There are an equal number of studies showing some benefit, no benefit, or some harm from this product." This may be a truthful statement, but surely is not a claim worth making.

b. How should FDA determine when evidence supporting a health claim is qualitatively weaker than the evidence against the claim?

CRN response: If there are 3 small studies in support of a claim and 3 large well-controlled studies against it, then it would not entirely truthful to describe these as "an equal number of studies for and against the claim." That statement would be justified only in cases where the studies for and against are of generally equal quality. FDA could require that a statement describing the weight of the evidence must reflect the quality as well as the quantity of studies available. For example, in this case, a truthful statement might be, "While 3 small case-control studies indicate a benefit for this product, three large well-controlled randomized trials showed no benefit."

c. Are there other circumstances in which health claims are inevitably misleading and cannot be made nondeceptive by qualifying language?

CRN response: If all the evidence is null or negative, or if there are no relevant studies or any other basis for a claim, then it would be inherently misleading even to mention a possible substance/disease relationship.

7. What safety information is necessary to prevent a health claim from being misleading? For example, such information might include side effects, drug and food interactions, and segments of the population who should not use the product or should consult a physician before doing so. When a product may have adverse effects unrelated to the subject of a scientifically valid health claim, is the claim misleading? Under what circumstances, if any, should the product be allowed to bear the claim?

CRN response: There is nothing in the *Pearson* decision, as CRN reads it, which requires FDA to change the safety considerations already expressed in the general requirements, for a substance that is the subject of a health claim urging increased levels of intake. However, FDA could take this opportunity to indicate how it would make a decision regarding the safe range of various ingredients, including any upper limits or cautionary language that may be needed. The calcium health claim provides an example of an existing health claim which includes an upper limit on quantity and a cautionary statement about not exceeding that quantity (under certain conditions). The fact that there are safety issues to be addressed does not render a claim misleading, but may render the substance ineligible for a claim at all, under the general requirements, or may result in a requirement for upper limits or cautionary statements.

8. What actions should the agency take to ensure that consumers receive all relevant information about the safety of products that bear health claims and about research on product safety?

CRN response: CRN does not believe FDA can take on the task of ensuring that consumers "receive all relevant information" about anything, including product safety. Safety within a given range of intakes should continue to be a condition for making a health claim. The goal should be to assure that products bearing health claims are safe

for their intended use, and that consumers receive appropriate cautions, if necessary, regarding the levels or conditions of use that are considered safe.

RESPONSE TO QUESTIONS POSED BY FDA REGARDING HEALTH CLAIMS ABOUT EFFECTS ON EXISTING DISEASES

1. Does the language and structure of the act restrict the permissible types of substance-disease relationships that can be described in a health claim? How should FDA interpret the health claim and drug provisions of the act and the medical food provisions of the Orphan Drug Amendments in relationship to each other?

CRN response: CRN does not believe the language of NLEA restricts the permissible types of health claims that may be made. Section 403(r) defines a health claim as a claim which "characterizes the relationship of any nutrient....to a disease or a health-related condition...." The nature of the relationship is not limited to reducing the risk of disease, as opposed to ameliorating symptoms of disease. Indeed, FDA has already approved health claims for several substances which have been shown to reduce cholesterol levels, an effect which FDA views as having an impact on a disease or a symptom of disease, in the context of structure/function statements. Elements of the calcium claim may also be viewed as treatment effects, since one important effect of calcium is to reduce the rate of bone loss during aging, thus ameliorating an existing condition (bone loss) that can lead to development of osteoporosis.

Under current health claim regulations, claims for medical foods are exempted from the health claims provisions, and this should continue to be the case. Under existing law and regulations, health claims are permitted under certain conditions despite the fact that they would have been considered drug claims prior to NLEA. This is true regardless of the nature of the health claims permitted, and would not change if FDA concludes correctly that the language of NLEA permits statements relating to existing symptoms or diseases as well as statements about reducing the risk of disease.

2. If FDA were to permit at least some claims about effects on an existing disease as health claims, what criteria should be used to determine when a claim is a permissible health claim and when it is a drug claim under section 201(g)(1)(B) of the act?

CRN response: A health claim is by definition a statement that would have been considered to be a drug claim prior to NLEA. In specifying the labeling that shall be used for current health claims, FDA has drawn the line between health claims and drug claims in terms of the language used. For example, health claims refer to "reducing the risk" of disease, and are not supposed to use terms found in the drug definition, such as "prevent" or "treat." This is to some degree an artificial distinction, but serves the purpose of creating health claim terminology that is distinguishable from drug terminology. A similar approach should be taken to developing language to be used for claims about effects on existing risk factors or symptoms of disease.

3. If FDA were to permit at least some disease treatment or mitigation claims as health claims, what about claims that are covered by an existing over-the-counter (OTC) drug monograph? For example, if there is an existing drug monograph on the use of a dietary ingredient in an OTC drug product to treat or mitigate disease, and the monograph concludes that the substance is not safe and effective for the intended use, should FDA still consider authorizing a health claim for the substances-disease relationship?

CRN response: CRN believes FDA should consider authorizing a health claim when there is evidence sufficient to support the claim, as described in existing or new general requirements for health claims. Those criteria may not be exactly the same as those used in the OTC review, and thus may justify review even if an OTC drug claim was not authorized. Also, new evidence may have emerged in the time since the OTC review. The possibility exists that an FDA review of a health claim on a topic covered by the OTC review may trigger re-evaluation of the OTC claim as well.